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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/461,580    12/15/99    GUARENTE

L    0050.161800

021005    HM12/1106  
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EXAMINER
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ZEMAN, R	
ART UNIT	PAPER NUMBER

1645

DATE MAILED:

11/06/01

*18*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/461,580

Applicant(s)

GUARENTE ET AL.

Examiner

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 December 1999.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 28-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I in Paper No. 17 is acknowledged.

The amendment filed on 8-23-2001 is also acknowledged. Claim 1 has been amended.

Claims 28-61 have been removed from consideration. Claims 1-27 are pending and currently under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide guidance that would allow one to carry out methods as claimed. The claimed methods are all predicated on the ability to discern and alter acetylation "statuses" of proteins. The specification fails to provide guidance as to what comprises an "acetylation status" or which proteins are affected by said status. It is equally silent on the differences between an acetylation status and a NAD-dependent acetylation status. Further, the specification fails to provide guidance on the how to alter said acetylation statuses or how to determine said statuses. Furthermore, the specification fails to provide guidance as to the roles the histone proteins and the various Sir2 proteins play in the claimed methods. Finally, the

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claimed methods indicate that the “removal of an acetyl group” plays a pivotal role but the specification fails to provide guidance as to which acetyl group is to be removed or the role the Sir2 proteins play in said removal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the term “altering the acetylation status” Alter it in what way? By what methods? Additionally, what is meant by the term “acetylation status”? What criteria are used to determine said status? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 1, 6, 11, 21, 24 and 25 are rendered vague and indefinite by the use of the term “NAD-dependent acetylation status” What is meant by the term “NAD-dependent acetylation status”? What criteria are used to determine said status? How does it differ from the “acetylation status” With regard to claim 1 how does the “acetylation status” consist essentially of “NAD-dependent acetylation”? What else does the “acetylation status” consist of? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the term “altering the activity of a Sir2 protein” Alter it in what way? By what methods? How is said activity measured?

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Additionally, does the term “a Sir2 protein” refer to a single protein molecule or a single protein species? As written, it is impossible to determine the metes and bounds of the claimed invention.

The method of claim 1 is vague and indefinite as it is lacking in positive active steps that define a process. Method claims should contain all of the steps necessary for carrying out the invention. Said claim merely recites the goal of said method and does not point out necessary features of the method or components of the method.

ω Claim 2 recites the limitation “the histone protein” in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 and 14 are rendered vague and indefinite by the use of the term “removal of an acetyl group”. Removal from where? By what? What role does the Sir2 protein play? Is removal of said acetyl group the “activity “ of the Sir2 protein? As written, it is impossible to determine the metes and bounds of the claimed invention.

ω Claims 8, 10, 15, 22 and 26 recite improper Markush language. The ultimate member of the Markush group should be preceded by the conjunction “and” when the group is preceded by the phrase “selected from the group consisting of”.

Claim 11 is rendered vague and indefinite by the use of the term “NAD compound”. It is unclear what is meant by said term

ω Claim 11 and 21 are rendered vague and indefinite by the use of the term “detecting the NAD-dependent status”. How is said status “detected”? As written, it is impossible to determine the metes and bounds of the claimed invention.

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Claim 11 and 21 are rendered vague and indefinite by the use of term "producing a combination". It is unclear what is meant by "a combination" nor is it understood how said combination is "produced".

Claims 12 and 13 are rendered vague and indefinite by the use of the term "activity of the Sir2 protein". It is unclear what "activity" Applicant is referring to.

Claim 21 is vague and indefinite since it is unclear how a change in the acetylation status correlates to an alteration in the lifespan of a cell? How is the lifespan altered?

Claim 24 is incomprehensible. What method is used to identify the "agent:?"

The instant claims are so confusing it is difficult to determine what is being claimed. Consequently, no rejection over prior art is offered at this time.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7911. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman  
November 5, 2001